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Quantifying the robustness of process manufacturing concept – A medical product case study

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ABSTRACT

Product robustness refers to the consistency of performance of all of the units produced. It is often the case that process manufactured products are not designed concurrently, so by the end of the product design phase the Process Manufacturing Concept (PMC) has yet to be decided. Allocating process capable tolerances to the product during the design phase is therefore not possible. The robustness of the concept (how capable it is to achieve the product specification), only becomes clear at this late stage and thus after testing and iteration. In this article, a method for calculating the unit-to-unit robustness of an early-stage for a PMC is proposed. The method uses variability and adjustability information from the manufacturing concept in combination with sensitivity information from products' design to predict its functional performance variation. A Technology maturation factor for addressing varied process capability confidence was applied. A four-step process of Define, Connect, Map and Quantify was proposed for calculating PMC robustness and was tested for a wound-care product. The results show that the method was applicable and enabled PMC selection based on quantified robustness. The case also demonstrates that higher robustness is possible even at higher parameter variability with suitable measurements and adjustability.

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1. Introduction

Product robustness refers to performance consistency. A production system can be said to be producing a robust product when the variation between the units produced is low. Many robust design theories are available for achieving product robustness in discrete part and assembly production systems. In these cases, maintaining individual parts with dedicated quality control systems and also opportunities to absorb their variations in the assembly process are present. For process manufacturing, making components and assembling them is a continuous and often simultaneous process. Ingredients preparation, heating, curing and other time related parameters are typically involved in process manufacturing. Some aspects can be measured inline and some cannot. This situation builds more uncertainty when trying to achieve low unit to unit variation from the products being produced. Table 1 highlights the characteristics and differences between discrete and process manufacturing.

With respect to the aim of this article, the critical difference between process manufacturing concepts (PMCs) and discrete manufacturing concepts is the level of concurrency with the product design phase. In discrete manufacturing products, concurrent engineering practices are the standard, meaning the product and manufacturing concepts are defined at the same time, which

allows the design engineer to allocate tolerances to suit the process capabilities of the manufacturing processes. In contrast, process manufacturing product development is often sequential. This means at the time the product design is proposed, the manufacturing concept has yet to be determined and as a result, the estimated variation for the process stage is somewhat unknown. The process manufacturing concept is then proposed, selected and matured until variation is acceptable or minimized, with re-design occurring where the product functional requirements cannot be met, which comes at great delay. The aim of this article is to respond risk and uncertainty related to this sequential development by proposing and testing a method to calculate the unit-to-unit robustness for a PMC before it is built and matured. This will enable better concept selection and better understanding of the unit-to-unit product performance variation to be expected.

Research literature available on the topic of product robustness focuses on product design [1-5], assembly design [6] and production process design [7,8] for discrete manufacturing but does not address the products from process manufacturing. Most of the Functional Parameters (FPs) of process manufacturing products are not physical dimensions, like adhesive strength, permeability etc. linked to the Design Parameters (DPs) like porosity, layer thickness etc. and further linked to Process Parameters (PPs) like ingredient volume, mixing homogeneity, curing time, etc. The relationships of these PPs and DPs to FPs are defined at the product design stage. The limitation in process manufacturing is that the variation of PPs and DPs is not currently estimated until the time the PMC has been built and experimented.

Research on process technologies has focused on assessing flexibility [9] by measuring process agility to changes. Smart Process Manufacturing (SPM) [10] leverages information technology by establishing proactive communication and self-adjustability for each station to reduce final product rejection. Linking process variables to functional attributes and controlling the final product quality by inline process checks has been well discussed by Chemistry, Manufacturing and Controls (CMC) regulatory groups in pharmaceutical development for ensuring quality to be within specification [11]. Marianthi [12] explains the process of ensuring product quality by quantifying the sensitivity to variation of different process variables and fixing their variation limits to meet requirements in oral drug development. State of the art research on process manufacturing has focused on meeting the product performance through process controls or altering the process based on sensitivity, when parameters deviate.

The aim of this research is to demonstrate a method for reducing product performance variation by compensating one process variation for another. In addition this paper proposes a process for estimating product performance variation at the conceptual stage of process manufacturing. The calculations accounts variability and the adjustability of technology used, and the influence of each parameter at each station. The results allow for comparing multiple concepts and selection based on quantification of robustness.

Table 1 Basic difference of discrete and process manufacturing

| Discrete manufacturing | Process manufacturing |
|--|---|
| Each part is produced and transported to assembly line. | Parts are produced and assembled simultaneously with no clear distinction between the stages. |
| Design parameters are measured and maintained through statistical control systems. | In-line inspection is mostly gauging whether to accept or reject to move forward in the line |
| Assembly adjustments are possible with known part dimensions | With no parameter information present, no proactive adjustments possible. |

2. Unit to unit robustness

Before introducing a method, it is important to define the unit-to-unit robustness, which is: *“the amount of variation in the functional performance of a product from one unit produced to the next, for a particular production concept/system”*. It is not unique to quantify the unit-to-unit robustness for discrete manufactured products [8], however the considerations are different for process manufacture products. In process manufacturing, the product keeps progressing from sta-

tion to station changing its form from raw material to finished product. Variation is added at every station according to the variability of the process used, at the same time, the station may provide adjustability in its process parameters to compensate the variation from previous stations. As each product has its own characteristics, technology used at each station also contains uncertainty and must be consider when estimating the unit to unit robustness of a PMC.

The net variation at each station can be estimated using Eq. 1, 2 and 3.

$$\text{Variation contribution} = \text{Variability} \times \text{Sensitivity} \times \text{Technology maturity} \quad (1)$$

$$\text{Compensation ability} = \text{Adjustability} \times \text{Sensitivity} \times \text{Technology maturity} \quad (2)$$

$$\begin{aligned} \text{Net variation}(St_x) &= \text{Net variation}(St_{x-1}) \\ &+ \text{Var. contribution}(St_x) - \text{Compen. ability}(St_x) \end{aligned} \quad (3)$$

Net variation at the current station(St_x) is variation contribution of St_x plus the cumulation of previous stations after deducting the possible compensation at St_x available through adjustment. These components are described in the following subsections:

2.1 Sensitivity

This is the estimated gearing ratio of how the variation in PPs creates variation in DPs and then to FPs. The sensitivity of the FPs to the PPs is determined during product design. A net variation of FPs from its PPs can be arrived from Eq.4, Eq.5 and Eq. 6 in which s_{nsm} is net sensitivity of FP to PP_{nm} .

$$\Delta FP = (s_1 \cdot \Delta DP_1) + (s_2 \cdot \Delta DP_2) + \dots + (s_n \cdot \Delta DP_n) \quad (4)$$

$$\Delta DP_1 = (s_{11} \cdot \Delta PP_{11}) + (s_{12} \cdot \Delta PP_{12}) + \dots + (s_{nm} \cdot \Delta PP_{nm}) \quad (5)$$

$$\begin{aligned} \Delta FP &= (s_1 s_{11} \cdot \Delta PP_{11}) + (s_1 s_{12} \cdot \Delta PP_{12}) + \dots + (s_n s_{nm} \cdot \Delta PP_{nm}) + (s_2 s_{21} \cdot \Delta PP_{21}) \\ &+ (s_2 s_{22} \cdot \Delta PP_{22}) + \dots + (s_n s_{nm} \cdot \Delta PP_{nm}) \end{aligned} \quad (6)$$

2.2 Variation contribution

This is an estimate of the amount of variation (in the FPs) expected to be introduced at the station (variability x sensitivity). Contribution is directly proportional to the capability of the process used at each station at each PP. Fig 1 shows how process variation is reflected in FP through its sensitivity.

Variation contribution of all the PPs at each station on each FP can be calculated. This reveals which variable is impacting on each FP at which station and how much.

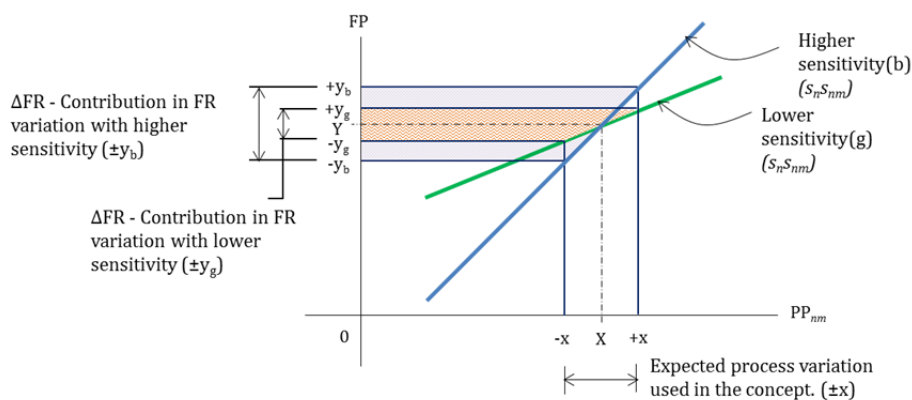


Fig. 1 Effect of PP on FP increases by increasing sensitivity gradient

2.3 Compensation ability

This is an estimate of how much variation in the product from previous stations that can be counteracted at the current station (adjustability x sensitivity). The ability to compensate is an important capability of Smart Process Manufacturing (SPM) concepts [13-15] which are characterized as “self-aware and proactive” as described by the process in Fig 2. Every station sends the information of product position/status proactively to the next station. The next station dynamically adjusts itself to suit the status of the product that it is about to receive. The overall system “smartness” is indicated by its proactive measurement frequency, information feed and speed of self-adjustment. Often passing the information is easy, but measuring may be difficult. Similarly, receiving information is quick but self-adjusting may be time consuming. However, the information fed will not be meaningful if the adjustment is not quick enough to fit into the production cycle time.

SPMs are focused on achieving assembly and handling variants. The same mechanism is used in this research for compensating variations. The measured amount of variation added at one station can be fed proactively to the next station, at which a self-adjustment mechanism compensates and nullifies the net variation.

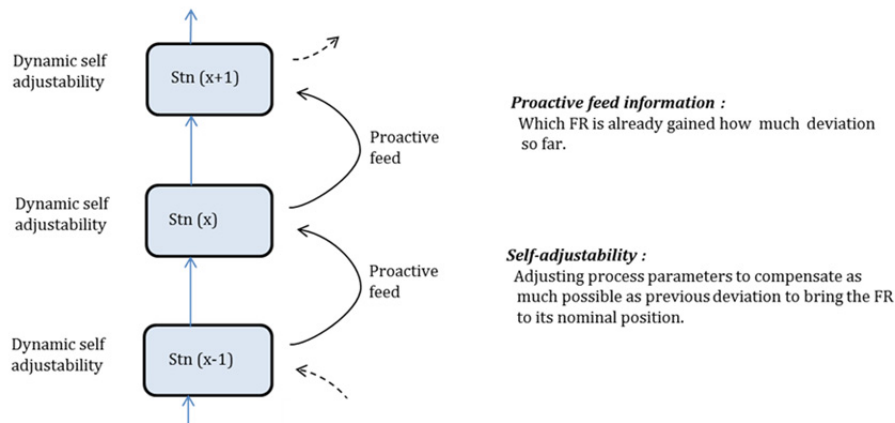


Fig. 2 Principle of Smart Process Manufacturing

The nature of the station and technology used in the concept indicates the adjustability of all the FPs involved. For example, pressure used at one station to achieve part thickness. By changing the pressure setting the thickness can vary. If the achieved density of the material is on the higher side of its tolerance from the mixture station, the pressure should be increased to get the thickness to its nominal, and vice-versa. Here adjustability means, ability of that station to self-adjust its pressure to the density by utilizing the information from its previous station. Quantification of FP adjustability is: how much thickness change can be accommodated through adjusting the pressure to its limit? The compensation opportunity of adjustability is calculated as shown in Eq. 7. An adjustability calculation is to be established for each FP at each station independently.

$$\Delta FP(thickness) = s(sensitivity) \cdot \Delta PP(pressure\ adjustability\ limit) \quad (7)$$

FP adjustability at each station helps to understand the remaining variation in the product. It is possible to compensate the variation (all or partially) by adjusting one station, then remaining variation will be added and passed on. The first station does not have any aim to compensate, it is the first one to contribute to variation. Some of the stations might have ZERO adjustability; for example, a punching tool used to perforate a metal sheet, the size of the holes cannot be changed every time, but if laser perforation is adopted, a numerical program can be dynamically changed for each unit in production. In the case of the punching tool concept, adjustability is zero. When adjustability is more than the contribution, it means all the variation of FP up until that station can be compensated.

2.4 Technology maturity

Manufacturing Concept reveals the technology of PP/DP generation at each station. Confidence of process capability data of that station depends on how mature the technology is. Even technology proven by another user often needs to pass through the learning process, when used in a new organization. This condition reduces the confidence, increases the variability and at the same time reduces the adjustability. A scientific Technology Readiness Assessment (TRA)[16] can be used to make a rough assessment. However, each industry uses their own scale. Table 2 shows the technology maturity level undersetting and a penalty factor (T_m) used in this study.

Table 2 Levels of technology maturation and corresponding penalty factor

| Level | Maturity | Penalty factor (T_m) |
|-------|---|--------------------------|
| 1 | In-house proven | 0 |
| 2 | Applied on similar product/competitor using | 0.25 |
| 3 | Applied on non-similar products/other field of industries | 0.5 |
| 4 | Theoretically proven, not yet applied for mass production | 0.75 |

Applying the penalty factor over contribution and adjustability are shown in Eq. 8 and Eq. 9

$$\text{Contribution: } \Delta FP = s \cdot \Delta PP \cdot (1 + T_m) \quad (8)$$

$$\text{Adjustability: } \Delta FP = s \cdot \Delta PP \cdot (1 - T_m) \quad (9)$$

3. Method for estimating robustness of a PMC

The method introduced in this section details the sequence of activities to calculate the unit-to-unit robustness for a PMC outlined in Fig. 3.

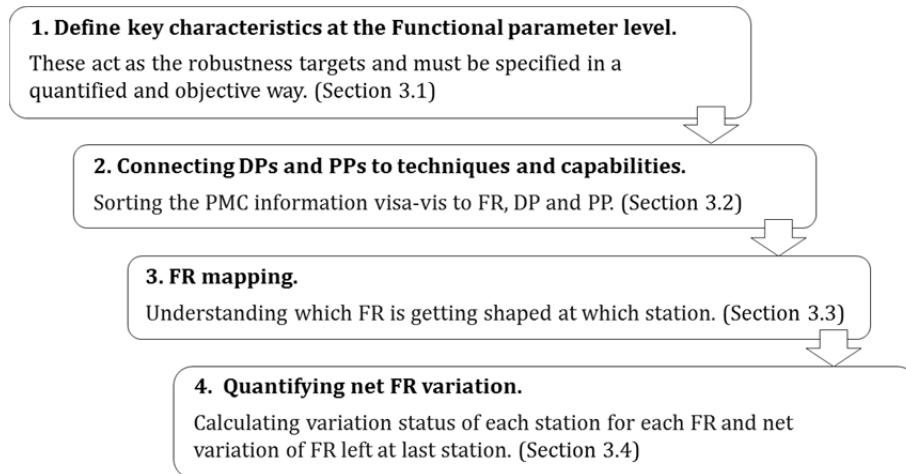


Fig. 3 Method of calculating Unit-to-unit robustness of a process manufacturing concept

3.1 Define all FPs – Ensuring no subjectivity

FPs are basically product performance attributes and need to be converted from a subjective qualitative formulation into an objective quantifiable form with tolerance limits[17]. All DPs which are linked to FPs should be specified in the product and its drawings, also in a quantifiable form. However, performance attributes may not always be explicitly *specified* as sometimes they are *implied*. For example, the alignment of two parts is a visual quality requirement. The drawing may indicate that they are aligned, but it may not be specified how much misalignment is acceptable. To achieve the alignment, manufacturing needs to identify it as a FP and then decide to the extent at which it is suitable to maintain it within tolerance limits. Table 3 shows the partial list of specified and implied FPs of the wound care product case.

Table 3 FPs with no subjectivity

| Specified FPs | | Acceptable variation |
|---------------|----------------------------------|----------------------------------|
| 1 | Permeability | $\pm 2 \text{ g/m}^2/\text{day}$ |
| 2 | Adhesive strength | $\pm 0.2 \text{ N}$ |
| ... | etc. | |
| Implied FPs | | |
| 1 | Non touch layer mismatch allowed | 0.3 mm |
| 2 | Logo print center shift allowed | 0.2 mm |
| ... | etc. | |

This list guides the application of suitable technology and measurement opportunities at each station, while generating concepts. Target values only indicate limits of acceptance; however the robustness approach aims to minimize the variation to zero.

3.2 Connecting DPs and PPs to techniques and capabilities

Table 4 shows how an FP cascades to DPs and PPs during the product design phase (simplified from case project). Once the product design phase has ended, the PMC then proposes how to achieve those DPs and PPs in a production setup. Information about the technology in the proposed PMC allows enable an estimation of the variability of the specific PPs.

Table 4 Cascading FP to DPs and PPs from design and linking to process information

| From product design | | From process manufacturing concept (PMC) | | |
|------------------------------------|---|--|-------------------------|-------------------------------|
| Heat dissipation (FP) | Technology | Variability | Adjustability | FP/DP/PP measurement facility |
| Material Porosity (DP1) | | | | |
| % of Ingredient 1 (PP11) | Automated mixer – Volume controlled with digital scale | $\pm 0.3 \%$ | $\pm 2 \%$ | Yes |
| Curing time (PP12) | Slow conveyor passing a fixed distance – speed controlled by analogue scale | $\pm 0.02 \text{ m/min}$ | $\pm 0.5 \text{ m/min}$ | No |
| Area of the exposure (DP2) | | | | |
| Cut-out area of upper layer (PP21) | Laser perforation – Programmable for hole size change | $\pm 0.2 \text{ mm}$ | $\pm 0.35 \text{ mm}$ | Yes |

3.3 FP mapping

The PMC explains the step-by-step progress in building the product. Different FPs start and finish their development at different stations. For example, the FP related to moisture absorption of the wound care product starts with material mixture ratio at the mixing station of silicone gel, passes through gel layer application and is finalized at the heating and pressurizing station. The product may pass through several stations in-between which have no influence on the FP. This allows to map where the FP is starting and ending over the PMC layout. Fig. 4 shows a schematic representation of a concept on which five hypothetical FPs is mapped. The transfer from one station to another must also be considered as part of DP/PP preparation like, time for chemical reaction, open air cooling, etc. sometimes, transfer adds an undesired contribution, such as the conveyor belt vibrations which can disturb the previous station work. This makes station to station travel also counted while understanding variations. Fig. 4 represents the mapping process.

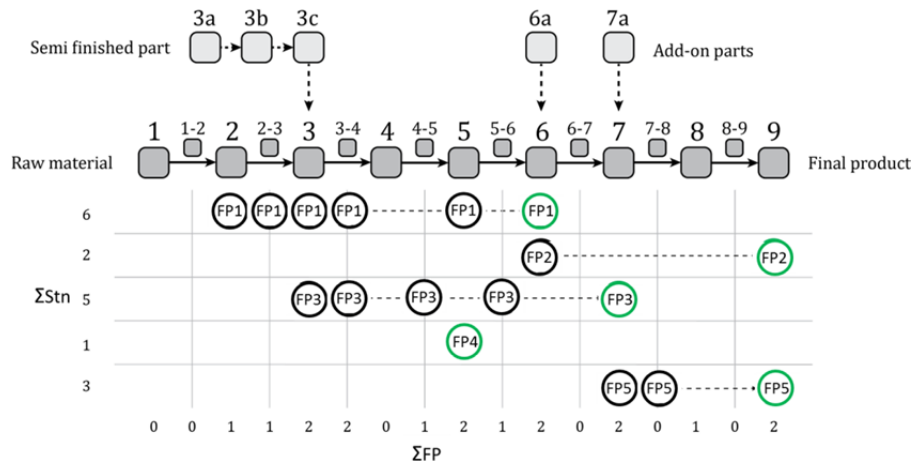


Fig. 4 All stations of a representative concept have been mapped with 5 hypothetical FPs

3.4 Quantifying net FP variation

In the next step, each FP is tabulate separately to facilitate the calculation of its expected variation. FP1 has been taken as an example from Fig. 4 and tabulated in Fig. 5 to show how the variation for the PMC is summed up. Identification of PP/DP/FP measurement ability and its information flow to the next adjustable station is required for the calculation. Sensitivity values, information flow and compensation abilities are different for each FP, needs unique calculation for each.

| Design | Manufacturing concept | | | | Robustness estimation | | |
|-------------------------|-----------------------|---------------------------|-----------------------|------------|---|---|---|
| Information from design | Process variability | Process adjustability | Technology maturation | Station no | FP1 | | |
| FP1 sensitivity to PP | $\pm Tol$ | $\pm adjustability$ range | penalty factor | | Contribution | Adjustability | Remaining variation while leaving the station |
| | $\pm pp_1$ | $\pm ad_1$ | Tm_1 | 1 | | | |
| | $\pm pp_{1-2}$ | $\pm ad_{1-2}$ | Tm_{1-2} | 1 - 2 | | | |
| S_{pp2} | $\pm pp_2$ | $\pm ad_2$ | Tm_2 | 2 | $C_2 = pp_2 \cdot S_{pp2} \cdot (1 + Tm_2)$ | | |
| S_{pp2-3} | $\pm pp_{2-3}$ | $\pm ad_{2-3}$ | Tm_{2-3} | 2 - 3 | $C_{2-3} = (pp_{2-3}) \cdot S_{pp2-3} \cdot (1 + Tm_{2-3})$ | | |
| S_{pp3} | $\pm pp_3$ | $\pm ad_3$ | Tm_3 | 3 | $C_3 = pp_3 \cdot S_{pp3} \cdot (1 + Tm_3)$ | $A_3 = ad_3 \cdot S_{pp3} \cdot (1 - Tm_3)$ | $R_3 = C_3 + (C_2 - A_3) \cdot *$ |
| S_{pp3-4} | $\pm pp_{3-4}$ | $\pm ad_{3-4}$ | Tm_{3-4} | 3 - 4 | $C_{3-4} = pp_{3-4} \cdot S_{pp3-4} \cdot (1 + Tm_{3-4})$ | | |
| | $\pm pp_4$ | $\pm ad_4$ | Tm_4 | 4 | | | |
| | $\pm pp_{4-5}$ | $\pm ad_{4-5}$ | Tm_{4-5} | 4 - 5 | | | |
| S_{pp5} | $\pm pp_5$ | $\pm ad_5$ | Tm_5 | 5 | $C_5 = pp_5 \cdot S_{pp5} \cdot (1 + Tm_5)$ | $A_5 = ad_5 \cdot S_{pp5} \cdot (1 - Tm_5)$ | $R_5 = C_5 + C_{3-4} + (R_3 - A_5) \cdot *$ |
| S_{pp6} | $\pm pp_6$ | $\pm ad_6$ | Tm_6 | 6 | $C_6 = pp_6 \cdot S_{pp6} \cdot (1 + Tm_6)$ | $A_6 = ad_6 \cdot S_{pp6} \cdot (1 - Tm_6)$ | $R_6 = C_6 + (R_5 - A_6) \cdot *$ |
| | $\pm pp_{6-7}$ | $\pm ad_{6-7}$ | Tm_{6-7} | 6 - 7 | | | |
| | $\pm pp_7$ | $\pm ad_7$ | Tm_7 | 7 | | | |
| | $\pm pp_{7-8}$ | $\pm ad_{7-8}$ | Tm_{7-8} | 7 - 8 | | | |
| | $\pm pp_8$ | $\pm ad_8$ | Tm_8 | 8 | | | |
| | $\pm pp_{8-9}$ | $\pm ad_{8-9}$ | Tm_{8-9} | 8 - 9 | | | |
| | $\pm pp_9$ | $\pm ad_9$ | Tm_9 | 9 | | | |

Net FP1 variation = R6

Fig. 5 Understanding of FP variation and compensation through adjustability. Here station 2, 3 and 5 are capable of measuring and communicating FP status (red dashed line); station 3, 5 and 6 are capable of self-adjusting. This FP starts at station 2 and ends at station 6. When adjustability is higher than contribution, * brackets are negative then return to zero.

It is possible that PMC is estimated better in some FPs only. In these instances FP prioritization [18] can be applied for choosing the right concept. When sensitivities are not available precisely, a scaling system can be applied as suggested in Variation Mode and Effect Analysis (VMEA)[19]. In order to achieve accurate results, there are a few considerations that need to be made when applying the proposed method, such as:

- Whether the measurement ability of a station is limited to the status of its own PP rather than the status of the FP.
- That the adjustability accuracy may also need to be considered along with its range.
- When adjustability is higher than variation gained, it is underutilized.
- The technology maturity might be different for process capability and adjustability of the stations so the maturity factors may need to be aligned.

4. Case study

A wound care product designed for high volume production has been taken as a case study to exemplify the proposed process. The wound dressing consists of an absorbent layer (2) with a fluid repellent backing layer (1) on top and a wound contact layer (3) consisting of silicone adhesive underneath. A release liner (4) is peeled off before applying to the wound. Fig. 6 illustrates the layers of the case product.

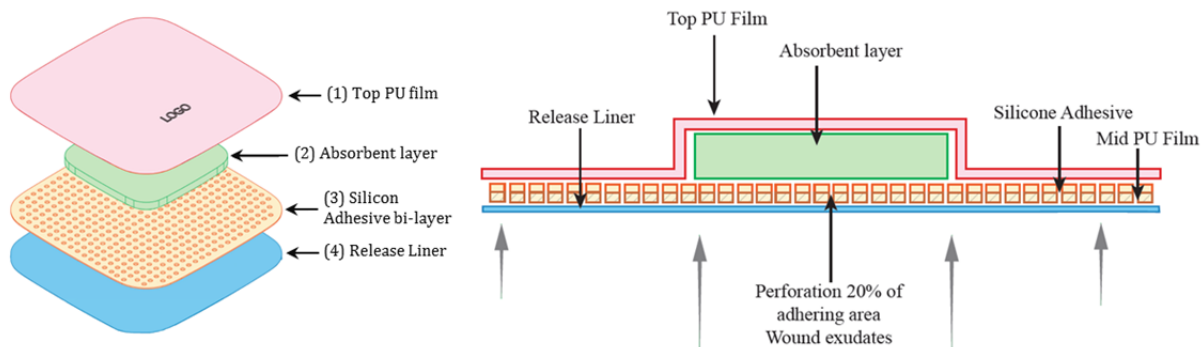


Fig. 6 Wound care product representation

Top PU protecting film is brought from supplier in rolls. A logo needs to be printed at a specific place and orientation on the film. The absorbent layer is a carried over component, produced in the same plant. The Silicon adhesive bi-layer consists of a permeable polyurethane film and silicone adhesive. Silicone adhesive is to be prepared with two of its ingredients and to be used within a certain period. Welding of top film and silicone layer can be done only after complete curing of adhesive silicone. The release liner contains of a simple PU film that, allows the user to peel-off easy, comes from supplier as a roll. Table 5 shows the breakup of FPs to their PPs with units and sensitivities collected from product design documentation.

Table 5 Two FRs cascaded to PPs

| FP | DP/PP | FP sensitivity |
|---|--|----------------|
| FP1. Moisture transmission ± 3 (g/mm ² /day) | | |
| | 1.1 Central holes diameter (mm) | 2 |
| | 1.2 Boarder holes diameter (mm) | 2 |
| | 1.3 Length of dressing (mm) | 1 |
| | 1.4 Width of dressing (mm) | 1 |
| | 1.5 Silicone thickness (mm) | 0.5 |
| | 1.6 Silicone heating rate (C ^o /s) | 0.25 |
| | 1.7 % of ingredient 1 | 0.4 |
| | 1.8 Silicone curing time | 0.1 |
| | 1.9 Absorbent layer thickness | -0.25 |
| | 1.10 Absorbent layer density | -0.15 |
| FP2. Wound exudates absorption ± 1.5 (g/mm ² /day) | | |
| | 2.1 Absorbent layer thickness (mm) | 0.8 |
| | 2.2 Central holes diameter (mm) | 3 |
| | 2.3 Absorbent layer density (g/cm ²) | -0.25 |

Two concepts evaluated for robustness are described:

Concept 1: A fully automatic line with computerized and analogue adjustment possibilities. Silicone gel adhesive preparation, layering and curing is the main cycle driver. A continuous roll film layer is passed until last to separate individual products. A robotic arm adds absorbent layer in the middle, synchronized to main film line. Fig. 7 shows the schematic representation of Concept 1.

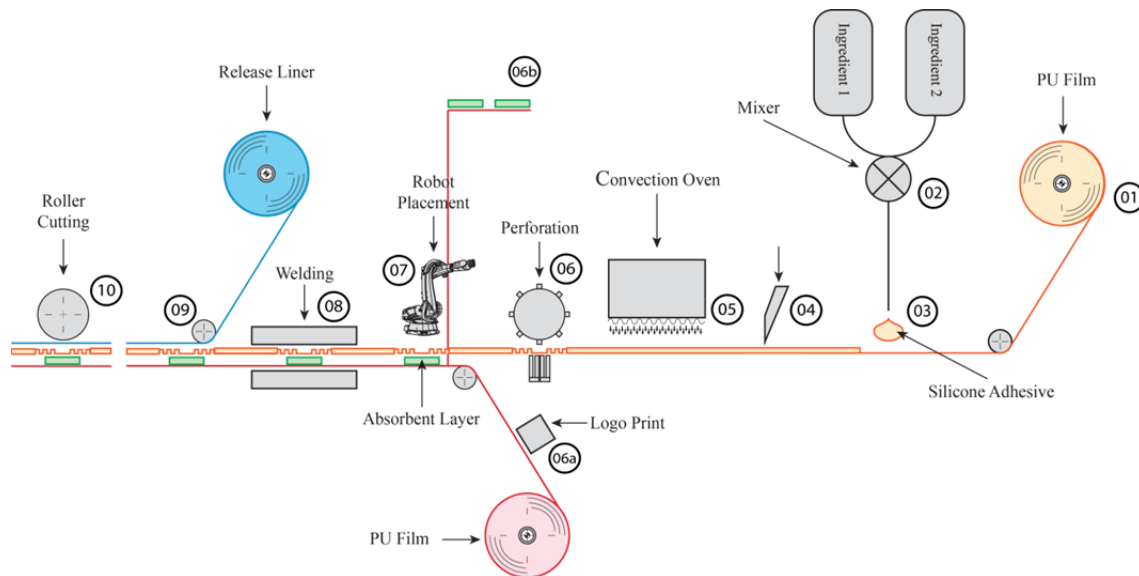


Fig. 7 Schematic representation of Concept 1

Concept 2: A fully automatic line. Silicone adhesive preparation, application and curing followed the principle of injection moulding. A robotic arm adds absorbent layer in the middle. Welding is performed as the last task, before separating the product from top film. Fig. 8 shows the schematic representation of Concept 2.

Estimations of the unit-to-unit robustness of the FPs for the two PMCs were made using the proposed method, as shown in the Table 6 and Table 7 for Concept 1 and 2, respectively.

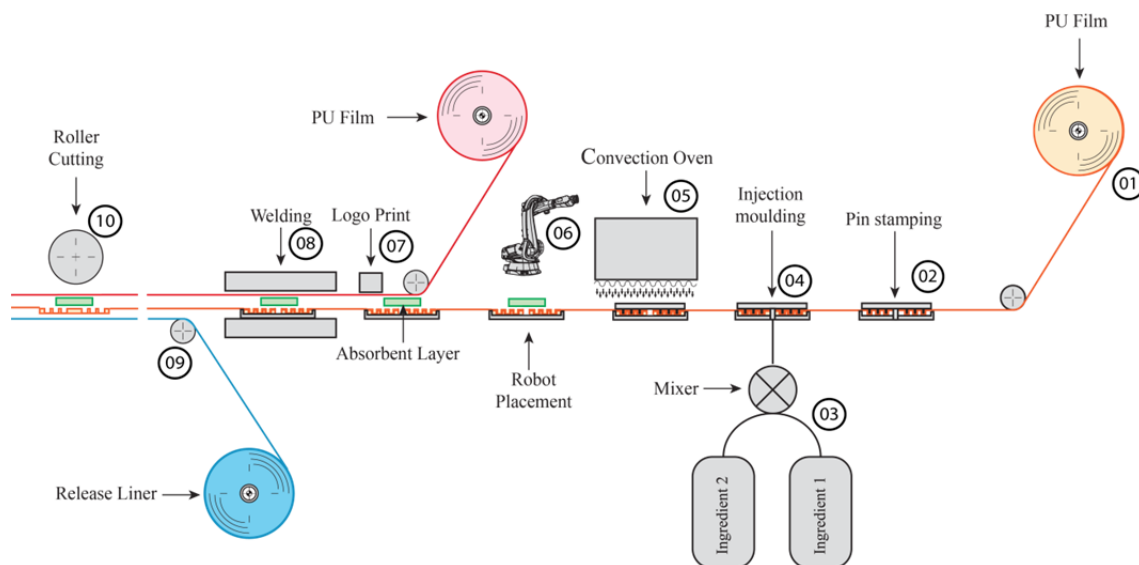


Fig. 8 Schematic representation of Concept 2

Table 6 FP1 and FP2 variation estimation over Concept 1

| Station No. | Effected PP | Variability \pm tol | Adjustability \pm adj | Technology maturation factor (Tm) | Measuring ability | FP1 – Quality acceptance is ± 3 | | | | FP2 – Quality acceptance is ± 1.5 | | | |
|---------------------|-------------|-----------------------|-------------------------|-----------------------------------|-------------------|-------------------------------------|--------------|---------------|---|---------------------------------------|--------------|---------------|-----------------------------|
| | | | | | | Sensitivity | Contribution | Adjustability | Net variation* | Sensitivity | Contribution | Adjustability | Net variation |
| 2 | 1.7 | 0.3 | 2 | 0 | Yes | 0.40 | 0.12 | NA | 0.12 | | | | |
| 4 | 1.5 | 0.2 | 0.5 | 0 | No | 0.50 | 0.10 | 0.25 | $0.1 + 0.12 - (0.12) = 0.1$ | | | | |
| 5 | 1.6 | 3 | 0 | 0.25 | No | 0.25 | 0.94 | | | | | | |
| | 1.8 | 1 | 3 | 0 | No | 0.10 | 0.10 | NA | $0.1 + 1.04 = 1.14$ | | | | |
| 6a | 1.9/2.1 | 0.5 | 0 | 0 | Yes | 0.25 | 0.13 | | $1.14 + 0.13 + 0.12 = 1.39$ | 0.80 | 0.40 | | |
| | 1.10/2.3 | 0.8 | 0 | 0 | Yes | 0.15 | 0.12 | | | 0.25 | 0.20 | | 0.60 |
| 6 | 1.1/2.2 | 0.2 | 0.35 | 0.25 | Yes | 2.00 | 0.50 | 0.53 | $1.39 + 0.5 + 0.5 - (0.13 + 0.12) = 2.14$ | 3.00 | 0.75 | 0.79 | $0.6 + 0.75 - (0.6) = 0.75$ |
| | 1.2 | 0.2 | 0.35 | 0.25 | Yes | 2.00 | 0.50 | NA | | | | | |
| 10 | 1.3 | 0.1 | 0 | 0 | No | 1.00 | 0.10 | | $2.14 + 0.1 + 0.1 = 2.34$ | | | | |
| | 1.4 | 0.1 | 0 | 0 | No | 1.00 | 0.10 | | | | | | |
| Net FP1 variation = | | | | | | ± 2.34 | | | | Net FP2 variation = | | | |
| | | | | | | | | | | ± 0.75 | | | |

Table 7 FP1 and FP2 variation estimation over Concept 2

| Station No. | Effected PP | Variability \pm tol | Adjustability \pm adj | Technology maturation factor (Tm) | Measuring ability | FP1 – Quality acceptance is ± 3 | | | | FP2 – Quality acceptance is ± 1.5 | | | |
|---------------------|-------------|-----------------------|-------------------------|-----------------------------------|-------------------|-------------------------------------|--------------|---------------|------------------------------------|---------------------------------------|--------------|---------------|---------------------------|
| | | | | | | Sensitivity | Contribution | Adjustability | Net variation | Sensitivity | Contribution | Adjustability | Net variation |
| 3 | 1.7 | 0.3 | 2 | 0 | Yes | 0.40 | 0.12 | NA | 0.12 | | | | |
| 4 | 1.1/2.2 | 0.1 | 0 | 0.5 | No | 2.00 | 0.30 | | | | | | |
| | 1.2 | 0.1 | 0 | 0.5 | No | 2.00 | 0.30 | | $0.12 + 0.3 + 0.3 + 0.08 = 0.80$ | 3 | 0.45 | | 0.45 |
| | 1.5 | 0.15 | 0 | 0 | No | 0.50 | 0.08 | | | | | | |
| 5 | 1.6 | 1 | 0 | 0.75 | No | 0.25 | 0.44 | | | | | | |
| | 1.8 | 1 | 3 | 0 | No | 0.10 | 0.10 | 0.30 | $0.8 + 0.44 + 0.1 - (0.12) = 1.22$ | | | | |
| 6 | 1.9/2.1 | 0.5 | 0 | 0 | No | 0.25 | 0.13 | | $1.22 + 0.13 + 0.12 = 1.47$ | 0.8 | 0.4 | | $0.45 + 0.4 + 0.2 = 1.05$ |
| | 1.10/2.3 | 0.8 | 0 | 0 | No | 0.15 | 0.12 | | | 0.25 | 0.2 | | |
| 10 | 1.3 | 0.1 | 0 | 0 | No | 1.00 | 0.10 | | $1.47 + 0.1 + 0.1 = 1.67$ | | | | |
| | 1.4 | 0.1 | 0 | 0 | No | 1.00 | 0.10 | | | | | | |
| Net FP1 variation = | | | | | | ± 1.67 | | | | Net FP2 variation = | | | |
| | | | | | | | | | | ± 1.05 | | | |

*In the calculation of Net variation, segment in () is compensation done by adjustability at that respective station. Value is linked to the measuring ability of previous stations

Concept 1: Measurement and communication ability is at 2, 6a and 6 stations; and adjustability is present at 2, 4, 5 and 6 stations. In case of FP1, adjustability of station 4 nullified contribution of station 2. Adjustability of station 5 could not be utilized, as no measurement and communication ability was present at station 4. Station 6 could compensate the contribution of station 6a. In case of FP2, station 6 could nullify all the previous contributions, leaving just its own contribution.

Concept 2: Measurement and communication ability is only available at station 3; and adjustability is at stations 3 and 5. In the case of FP1, adjustability of station 5 nullified station 3 contribution. The variation of FP1 was lower in comparison with Concept 1 due to less variability. In the case of FP2, no adjustability was available which, made the variation higher than Concept 1.

5. Discussion

The above method can be used to estimate the variation expected from a PMC that has been designed for significant detail. However, as well as calculating estimation of the expected variation it is possible to attain some indicators for the robustness of PMCs before they are fully detailed. For example, number of stations is a good early indicator for a PMC since in general, the higher the number of stations, the higher product variation, especially when product changes its reference point many times. A larger number of stations also means that the product need to travel a larger distance, leading to more uncontrolled variations. However it is possible to achieve higher robustness even at higher number of stations with higher compensation.

The proposed PMC robustness estimation method demands sensitivity values of each FP to each DP and PP. Estimation accuracy is highly influenced by accuracy of the sensitivity values.

Aligning the FR/DP/PP measurement at the stations is often a big challenge. Often measurements are indirect, that leads to more PPs join in the calculations, for example a solution concentricity is measured by its colour. This adds colour as a PP and concentricity change against colour change as sensitivity.

Recent developments through the industry 4.0 revolution focused on proactive communications are demanding of the manufacturing concepts on the same principle of adjustability [20, 21]. The proposed robustness quantification process is easy applicable for new generation industry 4.0 compatible manufacturing concepts.

6. Conclusion

The process of estimating FP variation at the concept stage by linking concept characteristics to variation and compensation is demonstrated through a wound care product. This gives the opportunity to select PMCs which have the potential to produce with lower variation in the product's FPs. The method allows visualization of the flow of variation, and gives an opportunity to improve the concept further. By adding compensating ability at a few stations, many stations can allow for higher variability, reducing the product cost while achieving a low rejection rate. It reduces the product development cycle time by eliminating many iterations when establishing a product line. A key success criterion of this process is its ability to support the mapping of performance variation of a production layout, station by station. This process is also adaptable for any type of product and process, but requires knowledge of the variability sources and their impact on performance from product design. This process applicable to products containing high degree process manufacturing products (drugs, soft drinks, etc.) where the process design conducted by product design and manufacturing teams together.

Information exchange between product design and manufacturing is vital for successful implementation of the proposed process, which could be further supported by defining documentation standards for sensitivity values of the product and variability in the manufacturing details. The authors recommend that product robustness achievement to be part of the formal stage-gate criteria when selecting/evaluating PMC. Further research will consider establishing guidelines for concurrent engineering to bridge robustness in design and manufacturing and best utilize Industry 4.0 standards for in-line measurements and adjustments.

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